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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
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[1] 510(k) Summary of Safety and Effectiveness

[2] Yulex Corporation
37860 W Smith-Enke Road
Maricopa, AZ 85239, USA
Telephone: (520) 381-2261
Fax: (520) 568-2556
Contact: Dr. Katrina Cornish, Senior VP Research and Development
Prepared on: May 13, 2008

[3] Trade Name: Yulex® Natural Rubber Examination Gloves
Common Name: Examination gloves
Classification Name: Patient Examination Glove, powder-free

[4] Substantial equivalence is claimed to the legally marketed device, a Class I powder-free latex patient examination glove, which meets all of the requirements of ASTM standard D3578-05.

[5] The device is described as a Class I powder-free patient examination glove, made from guayule natural rubber, which meets all of the requirements of ASTM standard D3578-05.

[6] A disposable device made from guayule natural rubber. The device may bear a trace amount of glove powder and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS, CONTINUED
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[7] The technological characteristics of the device, as compared to ASTM or equivalent standards per §807.92(a)(6), are:

Characteristic	Standard
Dimensions	Meets ASTM D 3578-05
Physical Properties	Meets ASTM D 3578-05
Freedom from Holes	Meets ASTM D 3578-05
Powder-free Residue	Meets ASTM D 3578-05
Protein Content	Meets ASTM D 3578-05
No *Hevea* Antigenic Protein	Per method in ASTM D 6499-03
Primary Skin Irritation	Passed testing per 16 CFR Part 1500.41, Method of Testing Primary Irritant Substances and ISO 10993-10:2002, "Tests for Irritation and Delayed-Type Hypersensitivity".
Repeated Patch Dermal Sensitization	Passed testing per ISO 10993-10:2002, "Tests for Irritation and Delayed-Type Hypersensitivity", modified to include longer induction exposure period for solid test articles.

[8] Performance test data is the same as for §807.92(a)(6) mentioned immediately above under Item [7].

[9] Clinical data not required for gloves.

[10] The device meets all ASTM requirements, biocompatibility requirements, FDA requirements, and labeling claims as indicated by the performance test data listed above under Item [7].

[11] Latex used to manufacture the device meets the requirements for Category 4 Latex defined by ASTM D 1076-06.

[12] Gloves do not contain *Hevea* antigenic protein.

Katrina Cornish

Dr. Katrina Cornish

May 13, 2008

Date

Premarket Notification 510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2008

Katrina Cornish, Ph.D,FAAAS
Senior Vice-President, Research and Development
Yulex Corporation
37860 W. Smith-Enke Road
Maricopa, Arizona 85238

Re: K063810
Trade/Device Name: Yulex® Natural Rubber Examination Gloves, Powder-Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: OIG
Dated: March 18, 2008
Received: March 20, 2008

Dear Dr. Cornish:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

Applicant: Yulex Corporation

510(k) Number: K063810

Device Name: Yulex® Natural Rubber Examination Gloves, Powder-Free

Indications for Use: A disposable device made from guayule natural rubber. The device may bear a trace amount of glove powder and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K063810